#25 Decl. E. Grim 3/28/03

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Tracy E. Grim, et al.	Examiner:	Marie Patterson
Serial No.	09/592,462	Group Art Unit:	3728
Filed:	June 9, 2000	Docket No.	480032-307
Title:	FOOTGEAR WITH PRESSURE RELIEF ZONES		

CERTIFICATE UNDER 37 CFR 1.8
I hereby certify that this correspondence and identified enclosures are being deposited with the United States Postal Service, first class mail, postage prepaid, under 37 C.F.R. 1.8 on the date indicated, and is addressed to the Commissioner for Patents, BOX: Non-Fee Amendment, Washington, D.C. 20231 on 3-10-03

Kristina S. Townsend

BOX: Non-Fee Amendment
Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL DECLARATION
OF TRACY E. GRIM

I, TRACY E. GRIM, hereby declare as follows:

1. I am one of the co-inventors in the above-identified patent application.

2. I hereby reaffirm the statements set forth in my prior Declarations in this application.

3. I have reviewed the communication from the U.S. Patent Office mailed December 20, 2002 and the reference, particularly the Foldes U.S. Pat. No. 4,095,353, the Ma U.S. Pat. No. 4,598,484 and the Kuhn U.S. Pat. No. 4,727,661.

4. Initially, it is noted that each of the three patents cited above have high pressure points where the upwardly extending rods would engage the foot.

5. Now, returning to the present invention, it is intended for use with patients who have tender feet, particularly diabetic patients. Diabetic patients frequently have swollen and tender feet with skin which loses resiliency, tears easily and is so very fragile that it reminds me of cigarette paper. Blood circulation to the feet is poor in diabetic patients. They are subject to

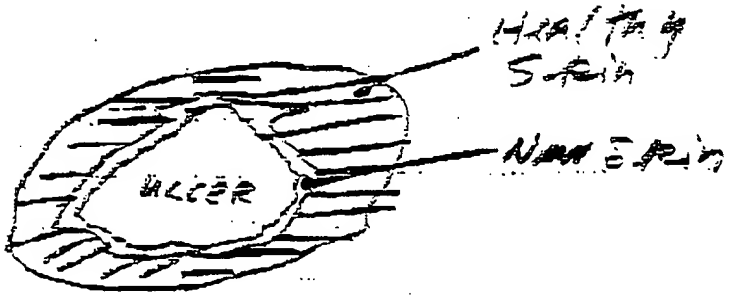
ulcers often brought on by high pressure points in conventional shoes. The foregoing problems are compounded by reduced sensory response and feelings of pain from the feet. As a result, ulcers may occur and expand, infection or gangrene may set in and there are an unusually high number of foot amputations arising from these serious problems.

6. On the following page are copies of medical text book photos showing foot ulcers on diabetic patents.

7. The constructions shown in the newly cited Ma, Foldes and Kuhn patents have many high pressure points and would be disastrous if used by diabetic patients, or other persons having swollen tender feet with week or thin skin on the lower surface of their feet. In my opinion the use of footgear of the type shown by the Ma, Kuhn and Foldes patents, would virtually shred the skin, or at least cause severe tissue tearing and damage, on the sole of the feet of severe diabetic patients.

8. However, the smooth continuous upper surface of the insole of our invention avoids high pressure points of conventional shoes as well as those of the newly cited references. Our insoles are useful without the removal of sections, as a preventive measure, and also, of course, to aid the healing of ulcers by the removal of sections where the ulcer is present.

9. The diagram relating to the re-growth of skin across an ulcer previously presented in an earlier Declaration is pertinent to the foregoing and is repeated here: Specifically, the recovery from ulcers on the feet of a diabetic patient, for example, is a slow, tedious process. Because the ulcer has very little blood supply and even less lymphatic return, ulcers on the feet tend to take months, sometimes years to heal. What happens is that the ulcerated area, if entirely free from pressure or frictional engagement, will slowly over a period of several weeks or months, grow an inwardly directed perimeter of new skin, which looks somewhat like this:



The growth of new skin is white in color, grows very slowly in cellular thickness and is very fragile. Any direct contact or rubbing involving the application of shear forces in the ulcerated area can tear the fragile cells and interrupt the slow growth process, and prevent healing.

10. From the foregoing analysis it is evident that the use of insoles of the type disclosed in the newly cited references having localized high pressure points would clearly prevent ulcer healing, and might well initiate ulcers in diabetic patents.

11. Turning to a broader view of the invention, each time a person steps forward they put extremely high forces and pressures to work, and these forces and pressures are concentrated on small areas of a foot. In a natural or normal gait the weight shifts from the heel to the mid-foot and then to the forefoot with push off. Particularly with the frequently over weight diabetic patients, this can amount to a load of 50 to 100 pounds per square inch (psi), accompanied by high shear forces. With loads at this high level of 50 psi to 100 psi, and the swollen tender feet, thin skin and poor circulation of many patients, the point type insole structures of Ma, Kuhn and Foldes would severely damage the feet. With our present invention, however, the pressure is spread out as high points on the foot sink into the insole, and shear forces are accommodated by yielding and flexing of the tall sections. Further, with the sections being directly adjacent one another or in engagement with one another, the shear forces do not build up and injure the skin, but instead the tall sections sway and flex, accommodating the shear forces without injury to the sole of the foot. Incidentally, as a preferred embodiment the hexagonal cross-sectional configuration is advantageous, in improving contact of the sections as they sway, and in providing relieved areas which conform to the shape of possible ulcers. Accordingly, peak pressures which could otherwise injure the foot or prevent healing are avoided.

12. The tall resilient sections could advantageously be used without removal of any sections, or with all sections permanently secured in place, as a preventive measure to avoid peak pressure points which might otherwise cause ulcers, or otherwise damage the foot.

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I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent application issuing thereon.

Respectfully submitted,

Date: 2-10-03

Tracy E. Grim